STERIVAP SL

Trade name **STERIVAP SL**
Type **SPSL**
Model **SPSL kk-npp**

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where:
kk chamber size (559, 636, 666, 669, 6612, 6615, 6618) in [dm]
n number of doors: 1, 2
pp way of supplying the chamber with steam

Medical device	Large steam sterilizer
Classification rule applied	Rule 16 according to Regulation, Annex VIII, Chapter III.
Risk class according to regulation (EU) 2017/745	IIa
BASIC UDI-DI	859420341SPSLMM
EMDN	Z12011380
GMDN	38671
MD	MD 1107
UMDNS	16141
MDA/MDN	MDA 0317
MDS	MDS 1004
MDT	MDT 2001; 2010; 2011
Manufacturer, Address	BMT Medical Technology s.r.o., Cejl 157/50, 602 00 Brno-Zabrdovice, Czech Rebublic

Contents

1 USEAGE

1.1 Intended for use

The STERIVAP®SL steam sterilizer is a device intended for use in healthcare for sterilization by moist heat of unpackaged and packaged medical devices, including invasive devices intended by their manufacturers for sterilization by moist heat.

Sterilization is a process which kills any viable microorganisms inclusive of their especially resistant spores. The sterilization inactivates viruses irreversibly. Sterilization kills also organisms, whose do not directly induce any disease of the patient, but might endanger him by weakening his organism. It is necessary to sterilize such objects which come in contact with injured skin and with mucosa:

- in open wounds (e.g. during operations),
- in body cavities (e.g. during endoscopy),
- on unprotected tissues (e.g. after burns),
- in case of changed immunoreaction (e.g. after transplantations) et.

Consequently, the sterilization units serve to sterilize goods guaranteeing their sterile state till the time of use.

1.1.1 Steam sterilization

During steam sterilization, saturated water steam condensates on the material being sterilized, what causes its heating. The condensate penetrates through the cellular shell of the microorganism directly to the cell nucleus and destroys it due to thermal energy transfer. From the said it is obvious that, inspite of a relatively short sterilization exposure and low temperature, the sterilization effect of saturated steam is very high.

Steam sterilization is suitable for sterilizing:

- textiles made of cotton and heat resistant textile blends,
- metal goods with sufficient corrosion resistance
- implants
- many articles made of rubber, plastics, ceramics and glass.

The used sterilization temperature is mostly 134 °C. Sensitive rubber articles, parts made of plastics, glass and sensitive mechanical appliances are sterilized at 121 °C. To assess objects that are to be sterilized in saturated water vapour follow the instructions for use of such objects manufacturers. In questionable cases, you should make sure at first whether such objects are resistant to increased temperature, moisture, and temperature and pressure changes resulting from the sterilization procedure.

1.1.2 Disinfection

STERIVAP®SL also supports disinfection programs.

1.1.3 Restrictions on use

The STERIVAP®SL steam sterilizer is not suitable for sterilizing the following material:

POZOR!

- organic materials such as wool, leather
- optical fibers and other thermolabile articles
- flammable and explosive material
- liquids in tightly closed bottles and containers
- infectious hospital waste (e.g. C-waste)
- pathogenic charge

Sterilization control

The sterilization process must be validated by its user

1.1.3.1 Check by chemical process test

Chemical process tests react by colour change already on the presence of the sterilization media and serve for distinguishing between goods prepared to sterilization and goods already sterilized. Every package unit must be provided with a chemical process test indicator (it is also possible to use a self-adhesive chemical process test indication tape, which is stuck onto the package containing goods to sterilize). This test cannot be used to prove that the sterilized load is really sterile!

1.1.3.2 Check by chemical test of sterilization

The chemical test of sterilization reacts by a colour change in case the required values of some or all sterilization cycle parameters have been reached. This test cannot be used to prove that the sterilized load is really sterile as well.

1.1.3.3 Check by means of the Bowie-Dick test (BD-test)

Perform the BD-test regularly every day before the beginning of sterilization, after having run the first sterilization cycle with an empty chamber. The BD-test confirms the correct course of the sterilization program (venting, fractional course of vacuum, sterilization temperature during the exposure, steam quality...). If you sterilize common porous materials in the device, it suffices to perform the BD-test according to EN ISO 11140-4. If you sterilize hollow objects, the BD-test must be performed using a process challenge device (PCD) according to EN 867-5.

1.1.3.4 Check build in the unit

Steam sterilizers are provided with the possibility to print a report on the course of the sterilization program and a record on the course of pressure and temperature. The mentioned prints serve as foundation for the documentation proving the quality of the sterilization process. The way of using these documents is determined by the person responsible for the operation of the unit.

1.1.3.5 Check by means of biological indicators

A check by means of biological indicators of living spores provide reliable evidence about the sterilizer fitness for use..

1.1.4 Preparation of the sterilizer load

Material must be appropriately cleaned before sterilization. Material is usually sterilized while being packed. Package material must be resistant to temperatures up to 140 °C and changes of pressure up to 1000 kPa/min. When saturated water steam enters the chamber, condensation of the steam on the loaded goods takes place. Yet, a large quantity of air and other non-condensable gases restrain an ideal transfer of thermal energy from steam onto the goods being sterilized. Removal of mentioned gases and securing satisfactory drying of the sterilized load belong to the most important tasks of the steam sterilization technology. The sterilized material plays an important role in this case.

Decisive parameters co-acting during sterilization:

- Quantity of heat supplied into the sterilizer load, i.e. the temperature rise, weight and specific heat of the loaded material.
- Flow resistance, i.e. the factor influencing the speed of air removal from the sterilizer load.
- Uneven distribution of moisture due to condensate dropping down during sterilization of instruments.

1.1.4.1 Textiles

Folded textiles consume a large quantity of thermal energy when being heated. Due to their large airflow resistance folded textiles hold back air. Therefore textile loads with layers oriented in the sterilization chamber horizontally should be sterilized only at fractional course of vacuum. In case of vertically arranged textile layers, the air removal from the space between the individual textile pieces is substantially simpler. Textile pieces should not be compressed each other, also their location in the sterilization container should be loose. The specific mass of standardly wrapped textiles is approximately 0.11 kg/dm3, what corresponds to approximately 5 - 6 kg/STM (STM = sterilization module).

1.1.4.2 Instruments

When heating heavy instruments a large quantity of condensate arises on their surface, which drops down and humidifies the other material being located in the lower part of the sterilization chamber. Therefore it is advantageous to locate heavy instruments on lower trays. The quantity of condensate is substantially dependent on the character and weight of the instruments itself. Articulated instruments should have been opened or disassembled before loading them into the chamber, what makes the removal of residual air and condensate from heavy accessible parts easier. Mutually connected instruments or their parts create narrow gaps, which are quickly filled with condensate during steam sterilization. The thermal energy, accumulated in the instrument, is transferred also to the condensate collected in the said gaps, which is being heated up to the sterilization temperature as well. But in comparison with direct heating by condensing saturated water steam this process requires much more time.

1.1.4.3 Rubber load

Rubber is principally sealing material. Sterility of rubber parts can be achieved on condition that the individual surfaces remain separated from each other. Rubber aprons or kerchiefs can be sterilized with the aid of thicker textile pieces inserted between the surfaces of rubber material; here textiles assist in penetration of steam. To avoid damage of rubber by heat, sterilization is performed at lower temperature of 121 °C and with longer sterilization exposure time. Having finished the sterilization cycle, it is necessary to remove the rubber load from the hot sterilization chamber as soon as possible.

1.1.4.4 Load of special material

A large quantity of condensate is created in **thick-wall hoses**. In case that the hoses are not laying horizontally, the condensate concentrates in the lowest part of the hose. Venting of deep cavities in catheters and in some instruments is very difficult. A lot of residual air and condensate remain between flat parts of the instrument if there is a narrow gap between them during sterilization. Such parts and hollow bodies shall be also sterilized with fractional vacuum pre cycles with a sufficiently long sterilization exposure.

In case of **trays** loaded with goods and stacked one over the other in the chamber it is necessary to secure suitable removal of residual air, and thus making penetration of steam easier, by insertion of sufficiently thick textile layers between the individual trays. Due to condensation of steam it would be very difficult to separate, after sterilization, the

trays stacked without using textile pads. Objects of dish or spoon shape should be turned with their mouths down.

Vessels with covers or other containers without open outlets can get deformed due to the alternation of steam pressure and vacuum, or they can be non-sterile. Such objects are not suitable for steam sterilization.

Empty bottles are recommended to be sterilized with their bottoms up, using the program with 121 °C. In the opposite case, the condensate accumulated during sterilization at the bottom of an empty bottle cools down very quickly during the drying in vacuum. Consequently a heavy heat stress arises in the glass, which could cause cracking of the bottle. Never put the bottles by their whole bottom's surface on a metal support.

Silicone prostheses, as well as some **endoscopes** may be sterilized in saturated water steam. Follow the instructions of their producer.

1.2 Fields of application

The STERIVAP®SL steam sterilizer is suitable for sterilizing medical and non-medical material.
This device is intended for use in both healthcare and non-medical areas.

Medical use

Only such goods can be processed, for the processing of which it is possible to prove the validation (Validation).

The STERIVAP®SL steam sterilizer can be equipped with a sterilization package of open solutions and is suitable for sterilization of the following non-medical products:

- Liquids in open or loosely closed containers

1.3 Designated users

The steam sterilizer STERIVAP®SL may be operated only by persons, who, on basis of their training or knowledge and practical experience, guarantee correct and proper opera-

tion. Workers in charge of using the sterilizer shall be trained for this activity and acquainted with the Instructions for use. The keeper is held responsible for proper training of the personnel in operating the sterilizer.

Regular training, including the names of the personnel designated to operate the sterilizer, must be recorded.

2 Standards (used, derived)

2.1 Guideline

- Directive 93/42/EWG on medical devices (until 25.05.2020)
- Directive 2017/745/EU on medical products (from 26.05.2020)
- Directive 2014/68/EU on pressure equipment (PED)
- Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment

Using the above guidelines, the requirements of the following guidelines are also included:

- Directive 2014/30/EU on electromagnetic compatibility
- Directive 2014/35/EU on electrical equipment (low voltage directive)
- Directive 2006/42/EG on machinery, if more specific than Directive 93/42 EWG Appendix I on medical devices

2.2 Product standards

2.2.1 Basic requirements

- ČSN EN 285 Sterilization - Steam sterilizers - Large sterilizers

2.2.2 Pressure equipment

- ČSN EN 13445 Unheated pressure vessels
- ČSN EN 14222 Stainless steel cylindrical boilers

2.2.3 Electrical safety

- ČSN EN 61010-1 Safety requirements for electrical measuring, control and laboratory equipment. Part 1: General requirements;
- ČSN EN 61010-2-040 Safety requirements for electrical measuring, control and laboratory equipment. Part 2-040: Particular requirements for sterilizers and cleaning equipment - disinfection used to treat medical supplies
- ČSN EN 60601-1: Medical electrical equipment - General requirements for basic safety and essential performance

2.2.4 Software

- ČSN EN 62304 Medical device software - Software life cycle processes

2.2.5 Applicability in terms of security, risk analysis

- ČSN EN 62366-1 Medical devices - Part 1: Application of applicability techniques to medical devices
- ČSN EN ISO 14971 - Medical devices - Application of risk management to medical devices

2.2.6 EMC requirements

- ČSN EN 61326-1 Electrical measuring, control and laboratory equipment - EMC requirements - Part 1: General requirements

2.3 Quality management standards

- ISO 13485 - Certification of medical device quality management system

Note: Other standards to which the above regulations refer and which may only be applicable in parts are not listed separately.

2.4 Testing, validation

- ISO 17665-1 Sterilization of medical devices Wet heat sterilization Part 1: Requirements for the development, validation and on-going control of a sterilization procedure for medical devices

3 Design

3.1 Design Input

The development of these devices took place in 2012-2015.
The individual stages of development were planned and reviewed:

Plan TR 2012_D_V1
Plan TR 2012_D_V2
Plan TR 2013_D_V1
Plan TR 2014_D_V1
Plan TR 2014_D_V2
Plan TR 2015_D_V1
Plan TR 2015_D_V2

VZ_1773, VZ_1775, VZ_1776, VZ_1779, VZ_1780, VZ_1782
Development request number 1/2011.

3.2 Design Output

BOMs, production and technological documents.
Message Release of the device to production, DV_1492
Checklist 6051-ch-201220.

4 Model line

The common features of the STERIVAP®SL model line are these:

- sterilizer with vertical door sliding
- with its own steam generator (ED)
- service area from the front - sterilizers can be arranged right next to each other
- one or two - door version (not right and left version)
- loading height 850 mm
- light indication of the sterilization cycle status

4.1 Technical parameters

The table lists the sizes of the devices (the marking is derived from the size of the pressure vessel)

No. mat.	Device designation	STE [5]	Usable space [1]	Elec. input [7]	Internal chamber dimen-sions[2]	Volume [3]	External di-mensions of the device [4]
010499419	STERIVAP 636-1V SL ED	2	600 x 300 x 600	16.5	670 x 350 x 700	160	2400 x 795 x 970
010499416	STERIVAP 636-2V SL ED	2	600 x 300 x 600	16.5	670 x 350 x 700	160	2400 x 795 x 990
010549370	STERIVAP 559-1V SL ED	4	500 x 500 x 900	24	508 x 508 x 990	254	2200 x 895 x 1270
010555077	STERIVAP 559-2V SL ED	4	500 x 500 x 900	24	508 x 508 x 990	254	2200 x 895 x 1290
010499269	STERIVAP 666-1V SL ED	4	600 x 600 x 600	24	702 x 652 x 690	314	2400 x 995 x 970
010499267	STERIVAP 666-2V SL ED	4	600 x 600 x 600	24	702 x 652 x 690	314	2400 x 995 x 990
010499266	STERIVAP 669-1V SL ED	6	600 x 600 x 900	38	702 x 652 x 990	453	2400 x 995 x 1270
010498185	STERIVAP 669-2V SL ED	6	600 x 600 x 900	38	702 x 652 x 990	453	2400 x 995 x 1290
010499431	STERIVAP 6612-1V SL ED	8	600 x 600 x 1200	47	702 x 652 x 1340	610	2400 x 995 x 1620
010499434	STERIVAP 6612-2V SL ED	8	600 x 600 x 1200	47	702 x 652 x 1340	610	2400 x 995 x 1640
	STERIVAP 6615-1V SL ED	10	600 x 600 x 1500	56	702 x 652 x 1640	748	2400 x 995 x 1920
	STERIVAP 6615-2V SL ED	10	600 x 600 x 1500	56	702 x 652 x 1640	748	2400 x 995 x 1940
010511256	STERIVAP 6618-1V SL ED	12	600 x 600 x 1800	56	702 x 652 x 1940	885	2400 x 995 x 2220
010509545	STERIVAP 6618-2V SL ED	12	600 x 600 x 1800	56	702 x 652 x 1940	885	2400 x 995 x 2240

Legend

[1] Usable space in mm (H x B x T)
[2] Internal dimensions of the chamber in mm (H x B x T)
[3] Chamber volume in litres
[4] External dimensions of the device in mm (H x B x T) Height including plinth 100 mm
[5] Batch size STJ (Sterilization units)
[6] Data in mm
[7] Electrical input in kW

Electrical parameters:

Operating voltage: 3 × 230/400 V ±10 %

Network frequency: 50/60 Hz ± 5 %

Installation categories of overvoltage: 2

Type of current: 3NPE

Medium acoustic power: <78 dB(A)

Environment conditions:

ambient temperature: + 5 to + 40 °C

maximum relative humidity: 85 % at 31 °C

maximum altitude: 3000 m

Further technical data and data for installation and connection of the device are given in the "Installation plan", which is prepared separately for each size.

Some parameters may vary depending on the design and destination.

5 Device description

5.1 Technical description

The STERIVAP®SL unit is a modern steam sterilizer with 1-12 STM of usable volume.

Technical features:

- single-door (single sided) or double-door (double sided) type,
- Built-in steam generator,
- fractional vacuum by means of a heavy-duty water-ring pump,
- sterilization chamber with a heated jacket made of stainless steel,
- material of the chamber AISI 316L,
- PLC, automatic microprocessor control (two microprocessors master and slave),
- check of the individual sterilization phases during the whole cycle,
- easy operation of programs via touch screen,
- LCD display showing commands for the operator, phases of the sterilization cycle, error messages, etc.,
- intuitive control and communication,
- built-in printer for printing reports on sterilization, records of pressure and temperature course and error messages,
- control of steam pressure by means of sensors independent on the atmospheric pressure,
- doubled pressure and temperature sensors for an independent check of the sterilization process,
- easy installation,
- easy and comfortable operation,
- modest maintenance,,
- external covering made of stainless steel,
- modern design,
- wide offer of the additional equipment (additive).

5.2 Pressure device

The pressure devices of the stabiliser are designed, produced and tested according to the procedures given by the EU Directive No. 2014/68/EU. Pressure devices of a sterilizer, are made as an assembly that is defined by piping schemes. Safety of operation of this assembly is connected with the working safety of the complete sterilizer. Inspection and periodical checks of the sterilizer pressure devices at the user's place are regulated by national regulations for operation of pressure devices.

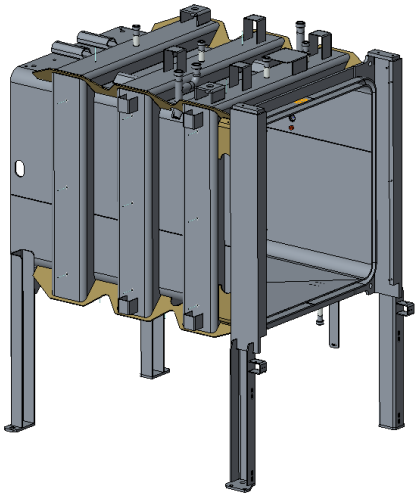
5.2.1 Assembly of the sterilizer pressure devices

- Pressure chamber of the sterilizer
- Electric steam generator
- Piping
- Safety and pressure equipment.

5.2.1.1 Pressure chamber

Pressure vessel, designed, checked for strength and cyclic stress and tested according to EN 13445 Unheated pressure vessels, the parts of which are made of CrNiMo or CrNiMoTi steel sheets:

- chamber shell - material no. 1.4404 (AISI 316L) EN 10028-7, inner walls are ground with surface quality Ra <1.25 micrometer.
- frame - material no. 1.4571 EN 10028-7
- jaws - material no. 1.4541 EN 10272
- reinforcements - material no. 1,4571 EN 10028-7
- door - material no. 1.4404 (AISI 316L) EN 10028-7, ground Ra <1.25 micrometer



The surface of the pressure vessel is covered with an effective thermal insulation made of ISOVER mineral wool coated with aluminium foil.

Depending on the version, the sterilization chamber is equipped with one or two sliding doors. Opening and closing is equipped with an electric drive. Sliding doors are sealed with a special sliding seal, material SILIKON.

Continuous verification of the pressure vessel during operation is governed by the maximum number of working cycles of the pressure vessel, which are shown on the customer's drawing - see tab.:

Mat. number	Document number	Pressure vessel type	Permitted number of sterilization cycles
010498539	10000797449	KOM 636-1V-SL	69 000
010554039	10001428646	KOM 636-2V-SL	85 000
010509159	10000880181	KOM 559-1V-SL	110 000
010554283	10001311311	KOM 559-2V-SL	200 000
010494050	10000763049	KOM 666-1V-SL	75 000
010551559	10001359923	KOM 666-2V-SL	100 000
010501393	10000822345	KOM 669-1V-SL	75 000
010550551	10001360899	KOM 669-2V-SL	100 000
010501575	10000823294	KOM 6612-1V-SL	75 000
010551991	10001353566	KOM 6612-2V-SL	100 000
010509900	10000887683	KOM 6618-1V-SL	75 000
010561567	10001425112	KOM 6618-2V-SL	100 000

5.2.1.2 Steam source

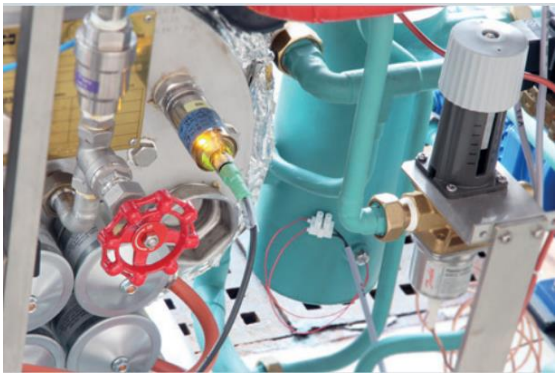
As a source of steam, STERIVAP®SL is equipped with a single-purpose electric generator, which meets the specifications of the standard ČSN EN 14222 Steam boilers made of stainless steel.

- The shell and lid are designed from CrNiMoTi steel, material no. 1,4571 (AISI 316 Ti).
- The surface of the pressure vessel is covered with an effective ISOVER mineral wool thermal insulation coated with aluminium foil.

The steam generator is used to produce pure steam from fully desalinated water. The steam generator can only be supplied with adequately treated, fully desalinated water. We recommend treatment on the principle of reverse osmosis. The generator is equipped with a device for thermal degassing of the generator feed water (option). Overviews of generators see tab.:

Mat. number	Device type	Generator power
010520083	STERIVAP 636-1/2V-SL ED	15 kW
010493200	STERIVAP 559-1/2V-SL ED	22,5 kW
010493200	STERIVAP 666-1/2V-SL ED	22,5 kW
010457642	STERIVAP 669-1/2V-SL ED	36 kW
010457644	STERIVAP 6612-1/2V-SL ED	45 kW
010510880	STERIVAP 6615-1/2V-SL ED	54 kW
010510880	STERIVAP 6618-1/2V-SL ED	54 kW

Equipment:



- Digital manometer for indication of steam generator pressure.
- Pressure indicator for regulation of steam overpressure.
- Safety switch for steam pressure limitation to 3 bar.
- Level indicator in the steam generator serves for switching-on of the supply pump and for protection of heating bodies in case there is a lack of supply water.
- Safety level indicator serves as protection of the steam generator and heating bodies in case there is a lack of supply water (electric steam generator).
- Regulation of water level in the supply water tank serves for regulation of water supply.
- The boiler is secured with a type tested safety valve, according to regulations.

The steam generator supplies the pump from a tank with a regulated water level. The minimum level in the storage tank is monitored by a level meter B86. When there is a lack of water, the generator's feed pump is blocked. The water level in the boiler is monitored by level switches. The protection of the heating elements is double. The lowest water level is ensured by the function of the safety level switch B91 (switching blocked). The level of the feed water is ensured by the level switch B90, which also has a protective function. If the level is not automatically replenished within the time limit (approx. 40 s), the generator heater will be switched off reversibly. If the level switch B90 is not flooded (water supplemented) for more than approx. 4 min., a fault will be declared. The generator is controlled by pressure using a pressure transducer. Excessive steam pressure values are prevented by the independent safety pressure limiter B31. Distilled, fully demineralized, or reverse osmosis water is required to operate the steam generator.. The data are usually read directly from meters located on the water desalination plant. Even when the generator is fed with treated water, the evaporation of boiler water gradually increases the salt concentration in the generator. The resulting salt concentration, which is harmful to the material of the generator pressure vessel, causes corrosion (so-called pitting corrosion). It is therefore necessary to desalinate the generator regularly. Partial desalination of the generator is performed automatically each time the feed water is added, when the desalination valve Y99 is open for about 3s. After a maximum of half a year, it is necessary to drain the generator (complete draining).

- tank - material 1.4301, volume 18l
- pump – 17l/min, 2800 rpm, 500W
- heating element 7,5 / 9kW R11/2" ET525 / 590, stainless steel

Required values for generator feed water and steam quality

Distilled, fully demineralized or reverse osmosis water is required for the steam generator feed water.

The EN 285 standard states a specific conductivity value of ≤5 µS/cm as the recommended value. However, SPSL devices do not require this conductivity value.

Contaminants	Condensate (steam)	Feed water (generator)
Evaporation residues	≤ 0,1 mg/kg	≤ 10 mg/l
Siliciom oxide SiO_2	≤ 0,1 mg/kg	≤ 1 mg/l
Iron	≤ 0,1 mg/kg	≤ 0,2 mg/l
Cadmium	≤ 0,005 mg/kg	≤ 0,005 mg/l
Lead	≤ 0,05 mg/kg	≤ 0,05 mg/l
Rest of heavy metals	≤ 0,1 mg/kg	≤ 0,1 mg/l
Chlorides (Cl^-)	≤ 0,1 mg/kg	≤ 2 mg/l
Phosphates (P_2O_5)	≤ 0,1 mg/kg	≤ 0,5 mg/l
Conductivity (at 20 °C)	≤ 3 µS/cm	≤ 5 µS/cm
pH value	5 up to 7	5 up to 7
Apperance	colourless clear without sediments	Colorless, clear,without sediments
Hardness	≤ 0,02 mmol/l	≤ 0,02 mmol/l

5.2.1.3 Piping

Design according to DIN EN 285.

Individual pressure devices of the assembly are interconnected with piping according to the schemes:

Mat. number	Description	Used for device sizes
11000241325	PIPE CONNECTION 66-SL	SP-SL 636, 559, 66xx
10000809631	PIPE CONNECTION VYV-SL	SP-SL 636, 559, 66xx

- The pipes and valves through which the steam flows are made of stainless steel.
- Stainless steel pipes DN6 – DN20, material 1.4404
- Copper pipes DN6 – DN40, material 2.0090
- The pipeline is color-coded and thermally insulated.

5.2.1.4 Safety and pressure equipment

It is described in the piping schemes and consists especially of:

Safety valve V1

Mat. number	Description	Producer
010096956	Safety valve G1/2",3,2 bar, type 06380	Herose

- Nominal inside diameter DN 12.
- Opening pressure 3,2 bar.

B90 (HW) – Level switch

Mat. number	Description	Producer
010510296	Liquiphant level switch FTL31 G3/4"	Endress+Hauser

● Regulates the working water level in the steam generator. The set water level is 70 mm over the upper edge of the heating coil. The level indicator contact is switched on after the regulated level value is reached.

B91 (NW) – Level switch

Mat. number	Description	Producer
010510296	Liquiphant level switch FTL31 G3/4"	Endress+Hauser

● Serves for emergency switching-off of the heating if the water level in the steam generator is low. The set water level is 32 mm over the upper edge of the heating coil. When reaching this level the level indicator contact is switched on and the automatics Master/Slave switches the heating off, an error is reported on the display, which requires an intervention of the operator. When flooded the level indicator contact is switched on.

PE3 – pressure indicator

Mat. number	Description	Producer
010443123	Pressure transducer JUMO MIDAS S05,0-10 bar	Jumo

● Serves for regulation of steam generator pressure

● Pressure measurement range: 0 to 10 bar.

Value, set in the Master/Slave automatics, is: 2,4 bar overpressure for switching the heating on (lower limit) Pressure regulation range: 2,8 bar overpressure for switching the heating off (upper limit).

B31 pressure switch

Mat. number	Description	Producer
010445540	Pressure switch RT200 0,2-6 bar	Danfoss

- Pressure switching range: 0,2 to 6 bar.
- Set value 3,0 bar.

Serves for independent emergency disconnecting of heating if the set limit of steam generator pressure is surpassed.

Pressure indicator PE

Mat. number	Description	Producer
010105184	Pressure transducer JUMO MIDAS S05, 0..4 bar	Jumo

- Pressure switching range: -1 to 3 bar.
- It is used to regulate the pressure in the shell and the chamber of the sterilization chamber.
- Values are processed in the Master-Slave automatics.

Temperature sensor PT100

Mat. number	Description	Producer
010443023	Temperature sensor 2xPT 100 BMSR-01-00	TRESTON s.r.o.

- It is used to control the temperature of the sterilization chamber.
- Values are processed in the Master-Slave automatics.

5.3 Vacuum system

The device is equipped with a powerful, quiet, two-stage, water ring pump with a pre-plate heat exchanger and a tank for circulating chilled water..

It achieves optimal water savings thanks to cold water circulation with integrated process-adapted temperature control.

- VACUUM PUMP VZ50 - 3~Motor 1,5 / 2,2 kW IE3
- VACUUM PUMP VZ110 - 3~Motor 3 / 4,55 kW IE3

Mat. number	Description	Used for device sizes
010563039	Vacuum pump VZ50-55.0034 [IE3]	SP-SL 636, 559, 666, 669, 6612
010528086	Vacuum pump VZ0110B41-55-012 [IE3]	SP-SL 6615, 6618

- PLATE HEAT EXCHANGER - plate material 1.4401 / AISI 316, Cu solder, working temperature max. 200 ° C, max. working pressure max. 16 bar.

Mat. number	Description	Used for device sizes
000621475	Plate heat exchanger 0,315 QM	SP-SL 636, 559, 666,
010032877	Heat Exchanger 0,74 m2	SP-SL 669, 6612, 6615, 6618

- CIRCULATION TANK (CYCLON) - material 1.4301

5.4 Air filter

Air is introduced into the sterilization chamber through an air filter. The filter is made of a material resistant to corrosion and biological degradation.

Mat. number	Description	Producer
000538626	Filter element AVF021 V002PVJ FRP	Pall

5.5 Device frame

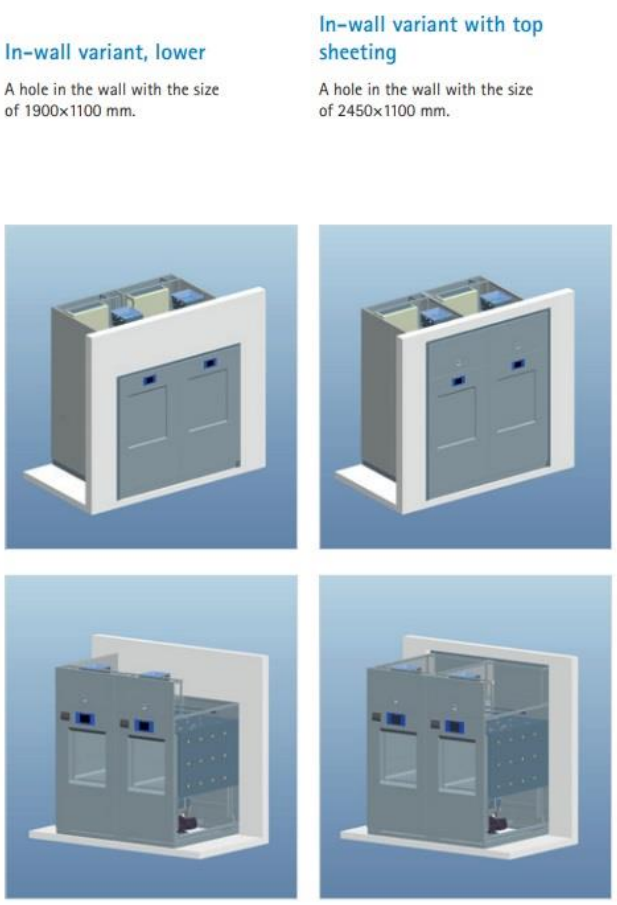
The STERIVAP SL device as a compact unit is assembled according to the design variant, selected by the customer, from several units:

- The basic skeleton of the device
- Switchboard superstructure
- Extension of the variant for the hole in the wall in height 1900 / 2450 mm
- Demi water tank frame

The frames are designed in stainless steel, material no. 1.4301 (AISI 304).
The basic frame of the device is used to place the pressure vessel and fix the closure frame. Superstructures and a tank frame for a steam generator are mounted on this frame.

The basic frame with additional frames allows two variants of installation in the building on the clean side at the customer:

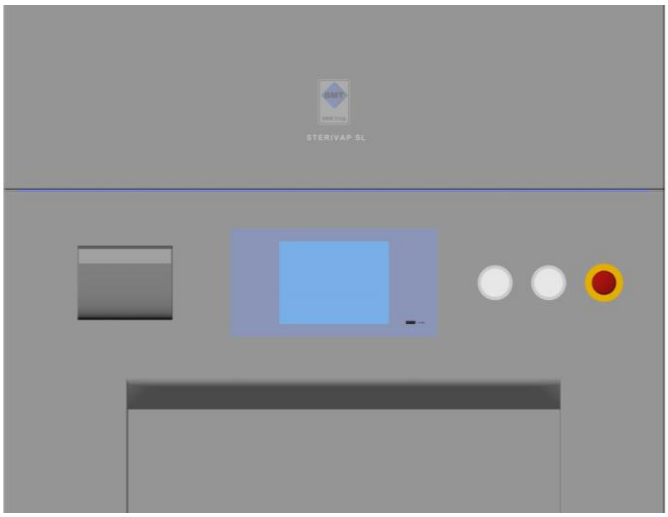
- variant for a lower hole in the wall (1900 x 1100mm) - standard design
- variant into the hole in the wall 2450 x 1100mm - optional design



5.6 Door closing

The chamber is closed by an automatic sliding vertical door made of CrNiMo steel (material no. 1.4404), the tightness of the door is ensured by a special replaceable rubber seal.
The door control mechanism is realized by an electric drive with springs and a mechanical clutch. The jaws of the chamber designed from a solid steel profile, which are a fixed part of the chamber, ensure the guidance of the door during movement but also guarantee a stable position during the sterilization cycle.. The door includes a mechanism - a safety bar, which protects against accidental collision of the door with the operator when closing.
Furthermore, the opening of the door during the program run and against the simultaneous opening of the loading and unloading side (for two-door devices) is treated.

5.7 Control panel



On the front cover of the device there is an ergonomically placed control panel, which is realized by an 8.4 "touch-screen display". Provides clear and simple operation on the loading side.
Next to it is a compact thermal printer, used to document sterilization processes.
As an option, a variant with an emergency button and one or two manometers is also prepared (see picture).

Not only the design accessory of the control panel - LED light bar - informs about the status of the device (end of cycle, fault).

Near the display, the operator and service technician have a USB connector, for easy transfer of data, programs, protocols, device configuration, etc...

Modern automatic consists of two built-in microprocessor PLC control systems (Master-Slave) with their own sensors for independent evaluation, sorting and documentation of work cycles.

On the export side of the two-door version, the control panel is implemented with a 5.7" touch screen.

The front cover, hung on 5 hinges, also serves as a service door and is equipped with a lock against unauthorized entry into the device.

The control panel offers a high level of operator comfort thanks to intuitive operation via a colour display with a touch screen and visualization of all operator inputs. The presentation of the process curves is displayed in a graphical online mode. Valve positions and machine states can be visualized. Valves and actuators can also be specifically controlled in the respective flowchart.

<u>Control screen options</u>

- switching the device on and off
- opening the sterilization chamber door
- choice of programs
- program interruption
- possibility to select the language for communication with the device

  On the screen in the menu / display settings.

  The SW is equipped with these language versions:

  Czech, German, Greek, English, Spanish, Estonian, French, Croatian, Hungarian, Kazakh, Lithuanian, Polish, Romanian, Russian, Slovak, Serbian and Chinese.

● clear digital display of pressure and temperature in the sterilization chamber (reference bottle), steam pressure in the sterilization chamber shell and in the steam generator
● clock - remaining program time indicator and real time indicator
● protocol history - integrated memory allows storage of up to tens of thousands of protocols (in graphical or numerical form)
● error history - this function allows error messages to be shown on the display
● additional comment - the device allows the operator to write additional comments to individual programs or cycles (e.g. product name, batch number, serial number, etc.), which will be included in the record from the printer
● logging - access rights enabling the setting of user rights for the use of the device
● visual and acoustic signalling of states and processes
● allows selection of preferred pressure and temperature units
● automatic start programming function
● possibility of automatic door opening after the end of the cycle

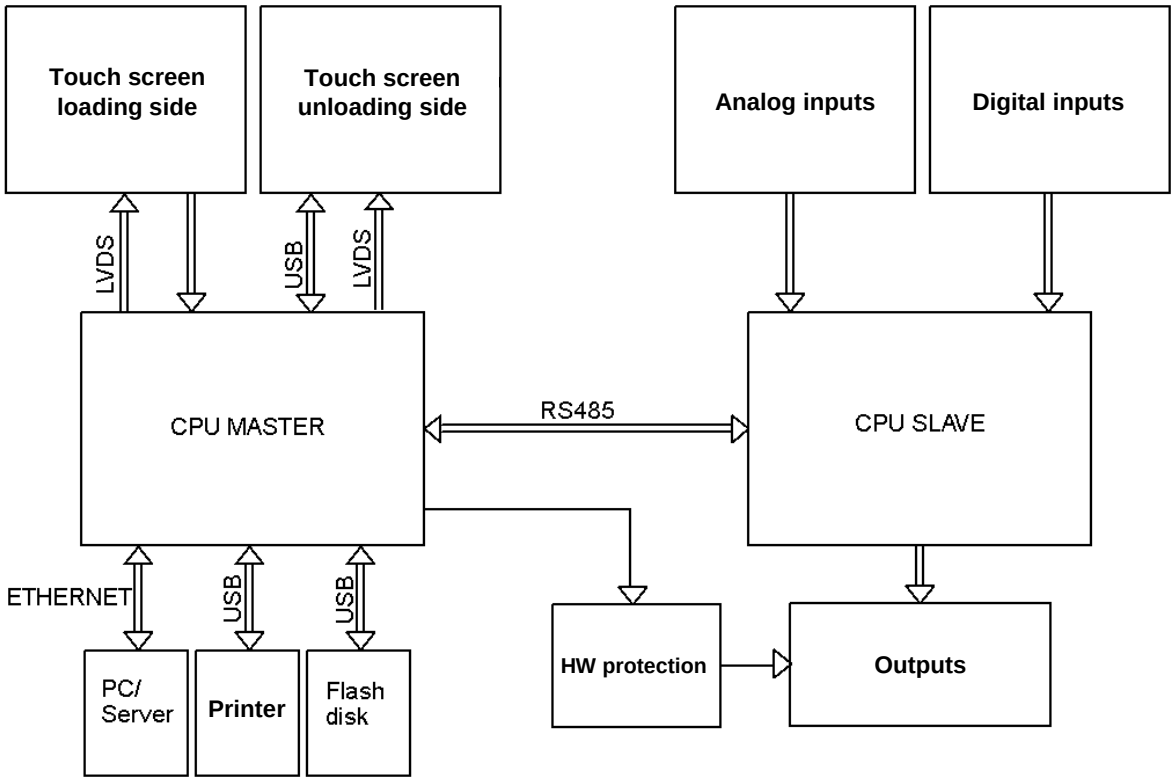
Printer

The sterilizer is equipped with a compact thermal printer on the unloading side, which transfers data from the sterilizer's automation to paper..
Among other things is documented:
Instrument number, batch number, date, time, program start, selected program, basic program steps with achieved pressure and temperature values (graph), start and end of exposure time, last vacuum test, last Bowie-Dick test, maintenance, sterilization result and error documentation.

● Fast, high-resolution printer with excellent print quality.
● Paper width 104 mm, scale corresponds to DIN EN 285 specifications (0.4 cm/min).

5.8 PLC & Software

An important part of the unit is the two-processor automation (master-slave), which performs the service of control, regulation and recording of the automatic course of operation and evaluates all operating and fault conditions.



CPU MASTER

The Master Software (Mst) has the following tasks:

- interactive communication with staff via a touch panel on the Mst side,
- control of internal communication with the Slave processor unit (Slv) via the RS 485 bus,
- storage of configuration data in flash memory,
- offset conservation for pressure and temperature sensors in flash memory,
- storage of program data (cycle data) in flash memory, including data for bacteriological filter (BAF),
- storing operational data in backed up RAM,
- saving cycle data to SD card,
- storage of rescue and identification data in EEPROM,
- sound signalization,

● communication with the printer,

● communication with external software system (SWS),

● supervisory measurement of pressure and temperature in the chamber,

● generating and managing alarms,

● door logic control - user settings, bacteriological filter (BAF), separation of potentially contaminated areas,

● Integration of Fo parameter increments.

CPU SLAVE

The Slave (Slv) software has the following tasks:

● measurement of analog quantities from temperature and pressure sensors,

● reading logical values,

● communication with power boards - output control,

● cycle control (sterilization cycle, vacuum test, ...)

● door sealing according to simple user settings of the door logic,

● door sealing according to the logic in terms of bacteriological filter and potential separation of contaminated areas,

● storing configuration data in flash memory,

● offset maintenance for pressure and temperature sensors in flash memory,

● storage of rescue and identification data in EEPROM,

● evaluation of error states,

● generating increments of the parameter Fo.

5.9 Electrical connection

Document number	Description	Use
10000744307	CONNECTION STERIVAP SL	SP-SL 559, 636, 66xx

5.10 Programs

We offer 50 program places in the basic software

The device is standardly equipped:

„Preheating program“ (134 °C/1min)

Standard programs:

- Unpacked tools 134 °C/4 min
- Packaged materials 134 °C/7 min
- Packaged materials with intensive drying 134 °C/7 min
- Packaged glass, rubber and plastic products 121 °C/20 min

Special programs with parameters according to customer specifications:

- Prions 134 °C/60 min
- Disinfection 105 °C/20 min
- Solutions in open bottles 121 °C/20 min, self-cooling
- „Arnold“ 100 °C
- Laparo, alloplasts, optics...
- Extra-long cavities
- Other special programs

Programs according to specific requirements must be validated by the customer! Highest safety when sterilizing solutions – In addition to standard operating and safety procedures and processes, the sterilization of solutions is also controlled by three independent systems – control of temperature and pressure in the sterilization chamber, temperature in the reference bottle and the minimum necessary time of the sterilization cycle. Only when all the above processes are completed is the program evaluated as completed and the system allows the chamber door to be opened.

Standard test programs for routine inspection:

- **Vacuum test (VT)**

– chamber airtightness test, length of balancing phase 5 min, test length 10 min

Expulsion of the air from the sterilization chamber, first of all from the goods to be sterilized, is the basic precondition of a successful sterilization, securing that all germs will be killed. In the opposite case, the remaining air would create “air nests“ inside the porous material and with regard to poor thermal conductivity of the air it would not be possible to

reach the necessary sterilization temperature in said nests. A minimum air leakage to the sterilizer during the period of vacuum is required. Therefore the program control is provided with a vacuum test to prove tightness of the sterilizer chamber under vacuum. The vacuum test shall be run with the sterilizer chamber empty and is performed as follows: first, the chamber is being evacuated, a 5 min. equalizing phase follows, and then the actual test, lasting 10 minutes, is started. After finishing VT program on the screen there appears the particular message containing the test result. VT is performed in cold operation status. In case of an inconvenient result, the VT must be repeated and if the tightness of the device does not conform even for the second time then it is necessary to shut down the sterilizer.

- **Bowie&Dick test 134**

– steam penetration test, 134 °C/3,5 min

The Bowie-Dick test is a test of steam penetration. It is performed at 134 °C/3,5 min checking temperature and time. The BD - test is used to ascertain whether the deaeration and the subsequent steaming of porous material is sufficient and whether the required temperature is obtained in the material during the whole period of sterilization exposure. The BD-test should be performed in a preheated state (e.g. after having run a sterilization cycle with the chamber empty).

5.11 Data archiving, data export

The device is equipped with an RJ45 connector for connection via Ethernet. The device can communicate with a PC via Ethernet. A special BMT software called Printer Archive is supplied for data collection on a PC. This software allows you to clearly collect all the data that the sterilizer sends to the printer on the computer's hard drive. Among other things, the Printer Archive allows you to print these records to a standard printer connected to a PC.

5.12 Ecosoft

The SPSL device has an optional EcoSoft function. This allows you to integrate the sterilizer into the EcoSoft system running on a network server via Ethernet. All complete sterilization cycles are then archived on the server and sterilization protocols are generated here. This is done in a uniform way for all devices of different types integrated into the network.

5.13 Safety

Hardware protection	Method of protection
Unlocking and starting the cap motor	Two independent pressure switches - the closure cannot be released unless there is atmospheric pressure in the sterilization chamber. The design of the door closure prevents the door from opening if there is overpressure in the chamber.
Filling steam into the door seal groove	Door properly closed → door plate position switches - it is not possible to inject steam into the seal groove unless the door closes perfectly.
Filling steam into the chamber	Door properly closed → door plate position switches - steam cannot be filled into the sterilization chamber unless the door closes perfectly. Door properly sealed → pressure switch blocks steam from entering the chamber. Reference pressure 1.3 bar, which must be reached in the door seal groove.
Steam generator heating	Level switch - the power supply is switched off if the level is below the permissible limit. An adjustable pressure switch switches off the power supply when the pressure exceeds 3 bar in the generator.

Additional security:

- The safety of the pressure vessel is ensured by the fact that the sterilization chamber and the door are designed, manufactured and tested according to the standard ČSN EN 13445 Unheated pressure vessels.
- Safety protection with safety valve against exceeding the maximum working overpressure.
- Door locking system during the work cycle by the automatic control system.
- Two-processor sterilization control system.
- In case of program interruption, automatic transition to a safe state.
- Warning error messages
- Independent hardware protection (monitoring of correct function of automatic)

  For safety reasons, outputs that can endanger the user or damage the device in the event of unwanted switching are blocked by relays that are switched by switches independent of the device's automatic.. Some outputs are blocked directly by these switches.

5.14 Critical components

Mat. number	Description	Producer
010096956	Safety valve G1/2",3,2 bar,type 06380	Herose
010443123	Pressure converter JUMO MIDAS S05,0-10bar	Jumo
010445540	Pressure switch RT200 0,2-6 bar	Danfoss
010105184	Pressure converter JUMO MIDAS S05, 0..4 bar	Jumo
010510296	Liquiphant level switch FTL31 G3/4"	Endress+Hauser / MMM GmbH
010443023	Temperature sensor 2xPT 100 BMSR-01-00	TRESTON s.r.o.
000538626	Filter element AVF021 V002PVJ FRP	Pall / MMM GmbH
010112369	Display 8,4" PROM-97G084S3N2F-2	Promate Electronic Co. / Avnet Europe
010493527	Display+touch 5,7" FG050722DSSWDGT1	Data image Co. / Koala El.
010445948	Module EMBEDDED TQMA53	TQ-Group / Oaxis Production
010445949	StarteKIT STKa53	TQ-Group / Oaxis Production
010497351	Electronics board SPL-KON1	Esika s.r.o.
010557227	Electronics board SPL-CPUS1-oživená	Esika s.r.o.
010557225	Electronics board SPL-AI_4-20mA1-oživená	Esika s.r.o.
010557219	Electronics board SPL-DI1-oživená	Esika s.r.o.
010557224	Electronics board SPL-AI-PT1-oživená	Esika s.r.o.
010557223	Electronics board SPL-PAC1-oživená	Esika s.r.o.
010557222	Electronics board SPL-PDC1-oživená	Esika s.r.o.
010445773	Electronics board K1,3B1	Esika s.r.o.
010563039	Vacuum pump VZ50-55.0034 [IE3]	SPECK
010528086	Vacuum pump VZ0110B41-55-012 [IE3]	SPECK
000621475	Plate heat exchanger 0,315 QM	FUNKE / MMM GmbH
010032877	Heat exchanger 0,74 m2	FUNKE / MMM GmbH
000628324	Pump SPECK NPY-2051.0843	SPECK
000016317	Pneumatic valve 2000 DN13	BÜRKERT / MMM GmbH
000082664	Piston valve DN13 BURKERT- stainless steel	BÜRKERT / MMM GmbH
000536569	Valve elmag 255A,DN 6,3/8",24 V/50 Hz	BÜRKERT
000031815	Condensate drain 1/2" BPT 13 A-E	SPIRAX SARCO

6 Accessories, additives

6.1 Material handling accessories

The material intended for sterilization or charge is either manually placed in the sterilization chamber space on fixed shelves or loaded on a trolley (BW). The customer chooses the equipment of the chamber according to the size and character of the charge.

The TW trolley is used between individual workplaces for the transport of material intended for sterilization and stored on a BW trolley.

6.1.1 Shelf system

Optional sterilization chamber equipment.

The steam sterilizer is then equipped for manual loading and unloading operation without loading and transport trolleys.

Equipment of the chamber with two shelves for inserting objects for sterilization, mounted on the casing of the sterilization chamber.

The shelf material is made of CrNi sheet steel, perforated for better condensate drainage.

Mat. no.	Description	Usable for design
010122937	Rack + 2 pcs stainless steel perforated shelves 636-1V	ED, FD
010122937	Rack + 2 pcs stainless steel perforated shelves 636-2V	ED, FD
010122936	Rack + 2 pcs stainless steel perforated shelves 559-1V	ED, FD
010122936	Rack + 2 pcs stainless steel perforated shelves 559-2V	ED, FD
010122938	Rack + 2 pcs stainless steel perforated shelves 666-1V	ED, FD
010122938	Rack + 2 pcs stainless steel perforated shelves 666-2V	ED, FD
010122939	Rack + 2 pcs stainless steel perforated shelves 669-1V	ED, FD
010122939	Rack + 2 pcs stainless steel perforated shelves 669-2V	ED, FD
010122940	Rack + 2 pcs stainless steel perforated shelves 6612-1V	ED, FD
010122940	Rack + 2 pcs stainless steel perforated shelves 6612-2V	ED, FD
-	Rack + 2 pcs stainless steel perforated shelves 6618-1V	ED, FD
-	Rack + 2 pcs stainless steel perforated shelves 6618-2V	ED, FD

6.1.2 BW trolleys, rails and other accessories for the chamber

Optional sterilization chamber equipment

The steam sterilizer is then equipped with chamber rails for the operator for manual loading and unloading by means of additional loading and transport trolleys..

6.1.2.1 Rails from CrNi steel

Mat. no.	Description	Usable for design
010122934	Tracks into chamber for loading cart	ED, FD

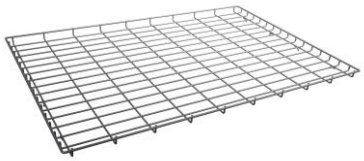
6.1.2.2 Loading cart BW - universal

Mat. no.	Description	Usable for design
-	Loading cart BW 636-1V Universal	ED, FD
-	Loading cart BW 636-2V Universal	ED, FD
010123129	Loading cart BW 559-1V Universal	ED, FD
010123129	Loading cart BW 559-2V Universal	ED, FD
010123131	Loading cart BW 666-1V Universal	ED, FD
010123131	Loading cart BW 666-2V Universal	ED, FD
010123132	Loading cart BW 669-1V Universal	ED, FD
010123132	Loading cart BW 669-2V Universal	ED, FD
010123133	Loading cart BW 6612-1V Universal	ED, FD
010123133	Loading cart BW 6612-2V Universal	ED, FD
010123134	Loading cart BW 6618-1V Universal	ED, FD
010123134	Loading cart BW 6618-2V Universal	ED, FD

6.1.2.3 BW loading cart - special

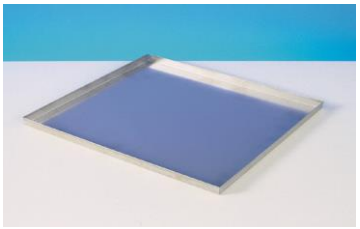
Mat. no.	Description	Usable for design
010123175	Loading cart BW 666-1V Special	ED, FD
010123175	Loading cart BW 666-1V Special	ED, FD
010123176	Loading cart BW 669-1V Special	ED, FD
010123176	Loading cart BW 669-1V Special	ED, FD

6.1.2.4 Stainless steel wire shelf for BW carts



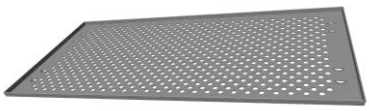
Mat. no.	Description	Usable for design
010123140	Additional stainless steel wire shelf 559-1V	ED, FD
010123140	Additional stainless steel wire shelf 559-2V	ED, FD
010123141	Additional stainless steel wire shelf 666-1V	ED, FD
010123141	Additional stainless steel wire shelf 666-2V	ED, FD
010123142	Additional stainless steel wire shelf 669-1V	ED, FD
010123142	Additional stainless steel wire shelf 669-2V	ED, FD
010123143	Additional stainless steel wire shelf 6612-1V	ED, FD
010123143	Additional stainless steel wire shelf 6612-2V	ED, FD
010123144	Additional stainless steel wire shelf 6618-1V	ED, FD
010123144	Additional stainless steel wire shelf 6618-2V	ED, FD

6.1.2.5 Drip tray for solutions



Mat. no.	Description	Usable for design
010123109	Tank against solution spillage 559-1V	ED, FD
010123109	Tank against solution spillage 559-2V	ED, FD
010123110	Tank against solution spillage 636-1V	ED, FD
010123110	Tank against solution spillage 636-2V	ED, FD
010123111	Tank against solution spillage 666-1V	ED, FD
010123111	Tank against solution spillage 666-2V	ED, FD
010123112	Tank against solution spillage 669-1V	ED, FD
010123112	Tank against solution spillage 669-2V	ED, FD
010123113	Tank against solution spillage 6612-1V	ED, FD
010123113	Tank against solution spillage 6612-2V	ED, FD
010123114	Tank against solution spillage 6618-1V	ED, FD
010123114	Tank against solution spillage 6618-2V	ED, FD

6.1.2.6 Stainless steel shelves for BW carts

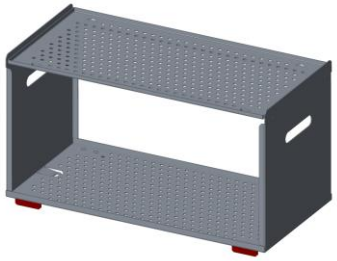


Mat. no.	Description	Usable for design
010123163	Additional stainless steel perforated shelf 559-1V	ED, FD
010123163	Additional stainless steel perforated shelf 559-2V	ED, FD
010123164	Additional stainless steel perforated shelf 666-1V	ED, FD
010123164	Additional stainless steel perforated shelf 666-2V	ED, FD
010123166	Additional stainless steel perforated shelf 669-1V	ED, FD
010123166	Additional stainless steel perforated shelf 669-2V	ED, FD
010123167	Additional stainless steel perforated shelf 6612-1V	ED, FD
010123167	Additional stainless steel perforated shelf 6612-2V	ED, FD
010123168	Additional stainless steel perforated shelf 6618-1V	ED, FD
010123168	Additional stainless steel perforated shelf 6618-2V	ED, FD

6.1.2.7 Hook for removing loading carts

Mat. no.	Description	Usable for design
010123105	Unloading hook for loading cart	ED, FD

6.1.2.8 Loading cart BW 636 (446) - with 2 fixed shelves



Mat. no.	Description	Usable for design
010123130	Loading cart BW 636, 446 - 2 fixed shelves	ED, FD

6.1.3 Transport trolleys (TW)

A number of TW trolleys were designed for the individual device sizes, primarily used for handling BW trolleys.

The transport trolley is equipped with a locking mechanism, which serves to fix the BW trolley during transport outside the sterilizer. The second mechanism, operated by a lever, is activated as soon as the TW trolley is connected to the rail in the sterilization chamber, thus ensuring a firm connection when handling the BW trolley.

The transport trolleys are equipped with wheels with an antistatic surface and the rear wheels are equipped with a brake.

The loading height of STERIVAPU®SL is 850 mm. The trolleys are set to this height from the factory, if necessary the height of the trolley can be individually adjusted to a limited extent.

Optional accessories.

Mat. no.	Description	Design
010123120	Transport trolley TW 636-1V	ED, FD
010123120	Transport trolley TW 636-2V	ED, FD
010123119	Transport trolley TW 559-1V	ED, FD
010123119	Transport trolley TW 559-2V	ED, FD
010123121	Transport trolley TW 666-1V	ED, FD
010123121	Transport trolley TW 666-2V	ED, FD
010123122	Transport trolley TW 669-1V	ED, FD
010123122	Transport trolley TW 669-2V	ED, FD
010123123	Transport trolley TW 6612-1V	ED, FD
010123123	Transport trolley TW 6612-2V	ED, FD
010123124	Transport trolley TW 6618-1V	ED, FD
010123124	Transport trolley TW 6618-2V	ED, FD

6.2 Device feet

STERIVAP®SL is equipped as standard with four legs screwed into the base frame, which enable height adjustment of the device and compensate for uneven floors. The lower plane of the device frame is set at a distance of 100 mm from the floor.

6.3 Panels

6.3.1 Side panels

The side panels, designed for mounting on the frame of the device from the side, are made of CrNi steel sheet, material 1.4301 (AISI304), ground on one side. The covering of the device consists of two to three sheets, depending on the total length of the device, on both sides. The complete covering of the free-standing device is marked as unabridged, shortened side covering panels are standard when installed in the wall.

6.3.1.1 Side panels unabridged

Mat. no.	Description	Usable for design
010123037	Side panelling unshortened 636-1 SL	ED, FD
010123037	Side panelling unshortened 636-2 SL	ED, FD
010123036	Side panelling unshortened 559-1 SL	ED, FD
010123036	Side panelling unshortened 559-2 SL	ED, FD
010123038	Side panelling unshortened 666-1 SL	ED, FD
010123038	Side panelling unshortened 666-2 SL	ED, FD
010123039	Side panelling unshortened 669-1 SL	ED, FD
010123039	Side panelling unshortened 669-2 SL	ED, FD
010123040	Side panelling unshortened 6612-1 SL	ED, FD
010123040	Side panelling unshortened 6612-2 SL	ED, FD
	Side panelling unshortened 6615-1 SL	ED, FD
	Side panelling unshortened 6615-2 SL	ED, FD
010123041	Side panelling unshortened 6618-1 SL	ED, FD
010123041	Side panelling unshortened 6618-2 SL	ED, FD

6.3.1.2 Side panels shortened

Mat. no.	Description	Usable for design
010123059	Side panelling shortened 636-2 SL	ED, FD
010123057	Side panelling shortened 559-2 SL	ED, FD
010123060	Side panelling shortened 666-2 SL	ED, FD
010123062	Side panelling shortened 669-2 SL	ED, FD
010123063	Side panelling shortened 6612-2 SL	ED, FD
	Side panelling shortened 6615-2 SL	ED, FD
010123064	Side panelling shortened 6618-2 SL	ED, FD

5.3.2 Top cover (roof)

The upper cladding (roof) is intended for mounting on side cladding sheets, it is used to close the device from the top and it is made of CrNi steel sheet, material 1.4301 (AISI304), ground on one side.

Mat. no.	Description	Usable for design
010123078	Top cover 636-1 SL	ED, FD
010123078	Top cover 636-2 SL	ED, FD
010123077	Top cover 559-1 SL	ED, FD
010123077	Top cover 559-2 SL	ED, FD
010123080	Top cover 666-1 SL	ED, FD
010123080	Top cover 666-2 SL	ED, FD
010123081	Top cover 669-1 SL	ED, FD
010123081	Top cover 669-2 SL	ED, FD
010123083	Top cover 6612-1 SL	ED, FD
010123083	Top cover 6612-2 SL	ED, FD
	Top cover 6615-1 SL	ED, FD
	Top cover 6615-2 SL	ED, FD
010123084	Top cover 6618-1 SL	ED, FD
010123084	Top cover 6618-2 SL	ED, FD

6.3.2 Sqm Additional panelling

Cladding panels, used to cover the gaps between the devices and the installation, individually according to the customer's situation. They are made of CrNi steel sheet, material 1.4301 (AISI304), ground on one side.

Mat. no.	Description	Usable for design
010123107	Sqm additional panelling	ED, FD

6.3.3 Cover strips

6.3.3.1 Cover strips on the clean side

Mat. no.	Description	Usable for design
010123091	Covering strips for clean side 636-2 SL	ED, FD
010123090	Covering strips for clean side 559-2 SL	ED, FD
010123092	Covering strips for clean side 666-2 SL	ED, FD
010123093	Covering strips for clean side 669-2 SL	ED, FD
010123094	Covering strips for clean side 6612-2 SL	ED, FD
	Covering strips for clean side 6615-2 SL	ED, FD
010123095	Covering strips for clean side 6618-2 SL	ED, FD

6.3.3.2 Cover strips on the unclean side

Mat. no.	Description	Usable for design
010511694	Covering strips for unclean side 636-2 SL	ED, FD
010511700	Covering strips for unclean side 559-2 SL	ED, FD
010511695	Covering strips for unclean side 666-2 SL	ED, FD
010511696	Covering strips for unclean side 669-2 SL	ED, FD
010511697	Covering strips for unclean side 6612-2 SL	ED, FD
	Covering strips for unclean side 6615-2 SL	ED, FD
010511698	Covering strips for unclean side 6618-2 SL	ED, FD

6.3.4 Height of the device on the unloading side 2450

Covering the device on the unloading side, including the upper superstructure, the upper openable cover with the lock and the light bar.

Mat. no.	Description	Usable for design
010554679	Height on unloading side 2450 mm	ED, FD

6.4 Bath under the device

50 mm high stainless steel tub with downward-facing drain, ready for introduction into the waste pipe. It is used to drain water from the sterilizer. They are made of CrNi steel sheet, material 1.4301 (AISI304)

Mat. no.	Description	Usable for design
010123020	Stainless steel vat under device 636-1V	ED, FD
010123020	Stainless steel vat under device 636-2V	ED, FD
010127817	Stainless steel vat under device 559-1V	ED, FD
010127817	Stainless steel vat under device 559-2V	ED, FD
010127817	Stainless steel vat under device 666-1V	ED, FD
010127817	Stainless steel vat under device 666-2V	ED, FD
010127818	Stainless steel vat under device 669-1V	ED, FD
010127818	Stainless steel vat under device 669-2V	ED, FD
010127819	Stainless steel vat under device 6612-1V	ED, FD
010127819	Stainless steel vat under device 6612-2V	ED, FD
010127820	Stainless steel vat under device 6618-1V	ED, FD
010127820	Stainless steel vat under device 6618-2V	ED, FD

6.5 Test systems

6.5.1 Non - condensable gas detector NCG (Air detector)

Additional equipment for monitoring leaks in the sterilization chamber.

Mat. no.	Description	Usable for design
010123015	Air detector	ED, FD

At a specific moment in the sterilization cycle, the temperature in the air detector chamber is monitored automatically by the sterilizer. If this temperature is lower than the threshold temperature (called the start temperature), it means that some content of non-condensible gases has been detected in the sterilization chamber. In this case, an error is reported and the cycle is aborted.
The start temperature is adjustable.

6.6 Electrical network variants

Sterilizer equipment for local supply 3 x 220 V at a frequency of 50 or 60 Hz, or supply voltage 480 V at a frequency of 60 Hz (UL design).

6.6.1 3NPE 3x220 V 50/60 Hz

Mat. no.	Description	Usable for design
010123028	Special voltage: 3x220V, 50 or 60 Hz	ED, FD

6.6.2 3NPE 3x480V 60Hz (UL-design)

Mat. no.	Description	Usable for design
010123029	Special voltage: 480V, 60 Hz, UL design	ED, FD

6.7 Degassing the generator feed water

Thermal degassing of feed water to reduce the proportion of non-condensible gases in pure steam.

Mat. no.	Description	Usable for design
010123006	Feed water thermal degassing	ED

6.8 Condensate cooling

Condensate cooling device that cools the condensate to a temperature of approx. 55 ° C by means of a thermoregulation valve.

Mat. no.	Description	Usable for design
010123004	Condensate cooling	ED, FD

6.9 Media monitoring

Additive for monitoring parameters (especially pressure) of connected media:

- compressed air
- KW water
- DEMI water
- steam (in the case of FD)

Mat. no.	Description	Usable for design
010123014	Media monitoring (air, water, demi w., steam)	ED, FD

6.10 Additional pressure gauge on the front panel

Analog manometer located next to the display on the front of the sterilizer, showing mainly the pressure in the chamber.

Mat. no.	Description	Usable for design
010123017	Pressure gauge (1x) placed in panel	ED, FD

6.11 STOP button

Hardware safety device for stopping the current program run.

Mat. no.	Description	Usable for design
010123026	Emergency STOP button - mechanical	ED, FD

6.12 Energy Manager (Steam manager)

An additional device for each sterilizer, which regulates the electricity consumption when connecting several sterilizers. For technical reasons, a maximum of three sterilizers can be in operation when the energy manager is activated.

The energy manager coordinates the chronological sequence of the program of the individual devices so that the input of the steam generator is as even as possible. Connected devices are connected to the network and are asked about the status of other devices before running the appropriate program. Depending on the result of this query, the device indicates that it is ready to run. The process step from which another device is allowed can be set depending on the connection performance. In addition, the integrated steam generator is operated with significantly lower heat output in phases when the need for steam is low (preparation for operation, depressurization, drying, removal). Process sequences and thus process reproducibility are not affected by the energy manager.

Mat. no.	Description	Usable for design
010123016	Steam manager - max. power take-off watch	ED

6.13 Backup power supply UPS

Backup power supply for control system. In the event of a power failure, the automation will remain active for a few minutes.

Mat. no.	Description	Usable for design
010554495	UPS - 405 W spare energy for the controller	ED, FD

6.14 Compressor

Mat. no.	Description	Usable for design
010483700	Air compressor incl. air receiver, casing, 230V/50Hz	ED, FD
010483006	Air compressor,receiver,casing-2 cylinders - PLUS-2V, 230/50hz	ED, FD

Replacement source of compressed air.

6.15 Sealing the door with compressed air

Mat. no.	Description	Usable for design
010487251	Door sealing by compressed air	ED, FD

6.16 Opening the sterilization chamber door in the event of a power failure

Mat. no.	Description	Usable for design
010493526	Emergency automatic door opening by power cut	ED, FD

The option allows the operator to perform a safe, relatively comfortable emergency opening of the sterilizer chamber door even in the event of a power failure.

It contains a backup source, a diaphragm pump that takes care of the removal of pressure in the grooves of the sterilization chamber door seal and an additional control element located on the front panel of the sterilizer.

The process itself is controlled by the automatic of the device.

6.17 Additional safety valve on the shell

Mat. no.	Description	Usable for design
010123027	Safety valve for steam jacket	ED, FD

6.18 Additional 32GB memory card

Mat. no.	Description	Usable for design
010499447	32 GB memory card	ED, FD

6.19 Piping disassembly for transportation

Mat. no.	Description	Usable for design
010123024	Piping disassembly for transportation	ED, FD

Option suitable for more demanding transport of devices. Eliminates damage caused by shocks during transport.

Includes disassembly of the pipe connection, including packaging.

7 Software options and special programs

7.1 Printer Archive, Audit Trail software

Software is an optional feature of the devices Sterivap-SL.

Mat. no.	Description	Usable for design
010123030	Printer Archive, Audit Trail software	ED, FD

A special BMT software called Printer Archive is supplied for data collection on a PC. This software allows you to clearly collect all the data that the sterilizer sends to the printer on the computer's hard drive.

Basic properties of the system:

- universal archiving of sterilization protocols on a computer
- central monitoring and recording of sterilization data at the workplace
- export of data to PDF or CSV format for further processing
- sending notifications via email about just finished sterilization, errors and more
- data integrity check

Connection:

- can be easily connected with a separate cable to steam sterilizers without any modifications to the devices (RS232, USB or Ethernet interface).

7.2 Tropical execution

Mat. no.	Description	Usable for design
010123018	Tropical execution (hot cooling water package)	ED, FD

Special program for areas with high ambient and cooling water temperatures.

Due to the increased vacuum switching points and additional fractionation, the operation can take place even under unfavourable conditions.

Sterilization temperature: 134°C

8 Combination with other devices

The product is not intended to interact with other medical devices.

The product can be connected to the accessories listed in chap. 6. and 7., the connection only allows data to be output from the device.

9 Dispatch and storage

9.1 Wrapping in foil

As a standard, STERIVAP®SL is transported on a pallet wrapped in a transparent foil.

9.2 Packaging in a wooden box

Mat. no.	Description	Usable for design
010129993	Seaworthy packaging in wooden box 636-1V	ED, FD
010129993	Seaworthy packaging in wooden box 636-2V	ED, FD
010129994	Seaworthy packaging in wooden box 559-1V	ED, FD
010129994	Seaworthy packaging in wooden box 559-2V	ED, FD
010129994	Seaworthy packaging in wooden box 666-1V	ED, FD
010129994	Seaworthy packaging in wooden box 666-2V	ED, FD
010129995	Seaworthy packaging in wooden box 669-1V	ED, FD
010129995	Seaworthy packaging in wooden box 669-2V	ED, FD
010129996	Seaworthy packaging in wooden box 6612-1V	ED, FD
010129996	Seaworthy packaging in wooden box 6612-2V	ED, FD
010129997	Seaworthy packaging in wooden box 6618-1V	ED, FD
010129997	Seaworthy packaging in wooden box 6618-2V	ED, FD

Dispatch of the sterilizer in a stable wooden package made of certified wood suitable for sea navigation.

The temperature during shipping conditions (short-term storage during transport) must be between -20 °C and +70 °C.

The storage temperature (long term storage in warehouses) must be between 0 °C and + 40 °C.

10 Service

Service operations in the territory of the Czech Republic, which follow the relevant standards. Acceptance and periodic inspections of the sterilizer at the user are governed by local national regulations for the operation of these devices.

10.1 Monthly inspection and maintenance

Mat. no.	Description	Usable for design
010129244	Monthly inspection and maintenance	ED, FD

The content of the monthly service inspection:

Functional check of the safety valve

10.2 Half-yearly inspection

Mat. no.	Description	Usable for design
010129246	Half-yearly inspection	ED, FD

It is necessary to put the steam sterilizer after 800 cycles, but no later than within every six months, to periodical service inspection made by a service technician.

The content of the half-yearly service inspection:

- Change the door sealing after 6 months (or after 800 cycles) for prevention.
- To inspect the tightness of screw-joints and pipeline connections..
- Check if the filter sleeve of the sterile air inlet is not damaged, eventually change it..
- To check and eventually readjust the setting of the aeration valve for the vacuum pump.
- Check for wear and, if necessary, replace the sliding door drive chain.
- To check the lowest underpressure (vacuum) reached by the vacuum pump.
- To test the devices for temperature measurement.
- To check the electric accessories, especially the tightening of the terminal of the protective wire.
- Check and adjust the end switches, the operation and the door lock overlaps (QPP 09-31).

● To examine the function of the door safety bar.

● To perform the test run of the apparatus and to check the program course for the correct setting of the times.

● Adjust the door sliding clutch to the tension of 100-150 N (measured during the door closing in the upper part of the door lifting).

● Generator sludge removal (complete drain).

● Open the storage tank of the supply water of generator, check visually the storage tank and clean it if necessary.

● Arrangement for the case of lack in water and pressure regulation, possibly blow through the device for water level indication.

● Check the pipe joints tightness and screw up the screwed joints.

● Check the water completion function (B90).

● Test the safety level limiter (B91).

● Test the safety pressure limiter (B31).

10.3 Annual inspection

Mat. no.	Description	Usable for design
010129247	Annual inspection	ED, FD

The content of the annual service inspection:

● Clean the sifter for capturing the dirt in the inlet and outlet pipes.

● Open the check valves, clean them and eventually change the sealing.

● Open and clean the condensate extract, eventually change the filler.

● Clean, eventually change the filter sleeve for sterile air inlet.

● Perform the re-calibration of sensors.

● Revision of electric parts. Inspection of electric wiring, especially the power supply, connecting and protecting terminals. It is checked the consistency of the wiring insulation (e.g. due to wearing through, burning etc.) and a firm connection of wires in the terminals. Resistance of protecting connection is R < 0,1 ohm. The resistance of power supply is not taken into account.

● Perform the check of the battery voltage.

● Clean the screens for impurities catchment in the inlet and outlet piping of generator - service. Check the inner space (visual control and/or by means of an endoscope or mirror)).

● Open and clean the back valves and replace the sealing if necessary.

10.4 Calibration

Mat. no.	Description	Usable for design
010129240	Calibration	ED, FD

Calibration of process-relevant sensors installed in a sterilizer with special test equipment such as oil bath, heat block, reference temperature measuring device and reference pressure transducer.

- Temperature sensor
- Pressure sensor

The results are documented.

All necessary adjustments are made and documented immediately.

10.5 Revision TNS

Inspections and tests of pressure vessels

Mat. no.	Description	Usable for design
010085148	Revision TNS	ED, FD

10.6 Electrical inspection

Mat. no.	Description	Usable for design
010092652	Electrical inspection	ED, FD

10.7 Pressure test

Mat. no.	Description	Usable for design
010495472	Pressure test	ED, FD

10.8 Validation

Validation of devices at the customer according to ČSN EN ISO 17665-1

Mat. no.	Description	Usable for design
010011475	Validation up to 12STJ	ED, FD

Basic characteristics

- validation in accordance with the standard ČSN EN ISO 17665-1 possibly with GMP requirements
- compilation of a validation plan, SAT (Site Acceptance Testing)
- installation qualification test program (IQ)
- operational qualification test program (OQ)
- functional qualification test program (PQ)
- final validation report

The tests are performed by the Accredited Testing Laboratory No. 1325 in accordance with the established working procedures, which are based on the relevant normative documents. Testing Laboratory BMT Medical Technology s.r.o. is accredited by the National Accreditation Body of the Czech Republic - the Czech Accreditation Institute, o.p.s. (ČIA) according to the ISO / IEC 17025 standard for testing steam and hot air sterilizers and temperature technology devices and evaluation of wet heat sterilization efficiency.
You will receive a written report of the validation with a certificate of compliance with the requirements for the wet heat sterilization process for validated batch configurations and test reports.

10.9 Revalidation

Mat. no.	Description	Usable for design
010129237	Revalidation up to 12STJ	ED, FD

Quality assurance in the processing of medical devices. Revalidation / renewed evaluation of the performance of the steam sterilization process according to DIN EN ISO 17665.
Annual evaluation (revalidation) is divided into:

- Preparation
- Functional evaluation (OQ)
- Performance rating (PQ)
- Final work
- Documentation

Preparation

Before starting a new inspection, the framework conditions and batch configurations are coordinated. The basis for this is a pre-sent questionnaire. The participants are an expert from BMT and at least one person appointed by the client (surgery management, central sterilization management, etc.). The basis are the configurations of the last inspection.
Process flow changes (additional tools, sieves, changed packaging and refills, media supply, etc.) must be documented and, if necessary, included in the reassessment process (additional tests charged separately if necessary).
The equipment, batch configuration and contact persons specified by the customer must be available within the agreed time.

Functional evaluation (OQ)

- Vacuum test with already connected reference sensors
- B&D simulation test with chemical indicator and thermocouples

according to DIN EN 285 specifications.

Performance rating (PQ)

- Load configuration according to revalidation plan (thermoelectric test including pressure test according to saturated steam curve).

Final work:

● Evaluation of results

● Final discussion of the results with the person appointed by the client

● Preparation of preliminary certificate (if required).

● Preparation of a reassessment report with final assessment and approval by the testing laboratory.

Documentation:

You will receive the following documentation documents from us in the revalidation folder:

● Summary with issue of the reassessment report

● Calibration protocols for the measurement technology used,

● Vacuum test protocol

● B&D test

● Configuration protocol

● Result of the reassessment

Note:

Other batch configurations are not included in the scope of the evaluation (eg changes in processing procedures / methods, other medical devices, changes in packaging, evaluation of special programs, etc.). In cases where thermoelectric measurement is not sufficient, it is necessary to perform an additional microbiological test.

This additional test is not included in the scope of the review.

Before re-evaluation, it is necessary to calibrate / adjust the temperature and pressure sensors built into the sterilizer.

For a new assessment, the operator must have up-to-date documentation on the condition of the feed water according to DIN EN 285 and, if applicable, steam condensate, to assess the quality of the sterilizing steam.

11 Guarantee

The warranty period is agreed by the contract of purchase. The guarantee shall apply to the defects of material or workmanship under the conditions that:

- The product was installed and used in accordance with the Instructions for use;
- The defect was not caused by incorrect maintenance, unqualified intervention into the device, or damage by external influences.

The guarantee shall not be applied to the natural wear and tear of the material and to the consumables, e.g. the door seal, materials for recording equipment, accumulators, etc.).

If a defect occurs, claim your right for a guarantee repair at the nearest service centre of BMT. Specify the name and type of the device, its production number and manifestation of the defect (error message, printer output).

If you meet the guarantee conditions, the service centre will, in its discretion, either repair the device or replace the defective part free of charge.

BMT guarantees that all technical documents and spare parts will be available for the period of 10 years from the introduction of the device to the market and a safe and functional operation of the device will thus be ensured for the said period.

After termination of the said period, BMT will be able to ensure a safe and functional operation of the device only upon a further contractual agreement.

In accordance with the EU Directive no. 85/374/EEC, BMT shall be responsible for any potential damage caused by a defect of the device for the period of 10 years from the introduction of the device to the market.

12 Previous product generations and competition analysis

12.1 Previous product generations

The STERIVAP®SL device is based on and builds on the previous generation of devices in the STERIVAP HP model line. Based on previous experience, the user interface was designed according to the previous model of this STERIVAP HP device and it is thus possible to consider this user interface as already standardized..

It has an instruction manual that was compiled according to the previous model of this STERIVAP HP device, so it is possible to consider this version of the instruction manual as already standardized..

From the point of view of user features, as well as its design, it is fully based on the experience of the previous model and the supervision of these devices placed on the market has not yet recorded any customer complaints regarding the user interface or instructions for use.

12.2 Competition analysis

Competitive analysis is one of the important parts of marketing planning. As part of the competition analysis in the proposals, the company identifies both its direct competitors and indirect or potential competitors.

The aim of the analysis is to obtain a detailed overview of competitors and their activities, the current market situation, the potential of the segment in design and development and especially to find new opportunities for business growth..

It may happen that in our competitors we come across products that have a much lower price than we can determine on our goods, or even will have goods that we do not even know about, or are similar to those that we would like to develop and add to our production portfolio.

Based on the analysis of the competition, the company-management usually defines its own marketing strategy for further direction of products development and improvement of competition ability.

13 Liquidation

The sterilizer consists of 90 % steel, 5 % electric material, 5 % other materials. An ecological liquidation of the disassembled unit shall be carried out by an authorized person.

When disposing of the sterilizer, it must first be dismantled:

- battery
- electronics on printed circuit boards
- display screens
- power supply cord

Follow these additional instructions:

For member states of the European Union

The product, which the user stops using and becomes unnecessary for him

and which is marked with a label

the user shuts down and notifies the seller (in the case of the Czech Republic, the manufacturer).

The sterilizer cannot be disposed of in municipal waste, its disposal is subject to the requirements of the European WEEE Directive (Waste Electric and Electronic Equipment).

For the countries outside of the European Union:

For proper disposal of the sterilizer, contact your local authorities or dealer for detailed information.